CareSource

PHARMACY POLICY STATEMENT **Georgia Medicaid**	
DRUG NAME	Sofosbuvir/velpatasvir (generic for Epclusa)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) Alternative preferred product includes Mavyret QUANTITY LIMIT— 28 for a 28 day supply
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Sofosbuvir/velpatasvir (generic for Epclusa) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEPATITIS C (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))

For **initial** authorization:

1. Member is treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
2. Member must be 18 years of age or older; AND
3. Member has genotype 1, 2, 3, 4, 5 or 6 (laboratory documentation required); AND
4. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
5. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
6. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required).
7. **Dosage allowed:** One tablet once daily for 12 weeks.

Note: Member's life expectancy must be no less than one year due to non-liver related comorbidities.

If member meets all the requirements listed above, the medication will be approved for 12 weeks.

For **reauthorization**:

1. Sofosbuvir/velpatasvir (generic for Epclusa) will not be reauthorized for continued therapy.

HEPATITIS C WITH DECOMPENSATED CIRRHOSIS (Child-Turcotte-Pugh Class B or C)

For **initial** authorization:

1. Member is treatment-naïve or treatment-experienced with decompensated cirrhosis (Child-Turcotte-Pugh Class B or C) who may or may not be a candidate for liver transplantation, including those with hepatocellular carcinoma; AND
2. Member must be 18 years of age or older; AND
3. Member has genotype 1, 2, 3, 4, or 6 (laboratory documentation required); AND
4. Member will be prescribed sofosbuvir/velpatasvir (generic for Epclusa) in combination with ribavirin (if ribavirin ineligible must submit documentation of **one** of the following results obtained within the past month: neutrophils < 750 cells/mm^3; hemoglobin < 10 g/dL; platelets < 50 000 cells/ mm^3; OR documented hypersensitivity to drugs used to treat HCV); AND
5. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
6. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
7. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required).
8. **Dosage allowed:** One tablet once daily for 12 weeks. If member is ribavirin ineligible and request is for genotype 1, 3, 4 or 6 sofosbuvir/velpatasvir (generic for Epclusa) may be approved for additional 12 weeks, not to exceed the total of 24 weeks treatment duration.

Note: Member's life expectancy must be no less than one year due to non-liver related comorbidities.

If member meets all the requirements listed above, the medication will be approved for 12 weeks.

For **reauthorization**:

1. Sofosbuvir/velpatasvir (generic for Epclusa) will not be reauthorized for continued therapy.

CareSource considers sofosbuvir/velpatasvir (generic for Epclusa) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Epclusa created.
06/08/2017	Fibrosis stage 2 and above covered.
11/22/2017	Medication status changed to non-preferred. Substance abuse program information is no longer required. Trial of preferred agent is required for members without cirrhosis or with compensated cirrhosis only.
12/07/2017	Criterion of "life expectancy not less than one year due to non-liver related comorbidities" removed from criteria and added in a form of the note. Hepatitis B testing is no longer required.
12/21/2017	Fibrosis score requirement was removed.
05/01/2019	Policy modified to Sofosbuvir/velpatasvir (generic for Epclusa); status changed to preferred product. Trial of Mavyret removed.

References:

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences Inc.; November, 2017.
2. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31). Retrieved from https://www.cdc.gov/hepatitis/hcv/index.htm.

3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C; 2017. Available at: https://www.hcvguidelines.org/.
4. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. Gastroenterology & Hepatology, 8(9), 605-607.

Effective date: 07/01/2019
Revised date: 05/01/2019